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| **TGHN-256x151px**  **Standard Operating Procedure** | | | **SOP No:**  **Version: 1**  **Effective Date:** | |
| **Title: Preparing Standard Operating Procedures (SOPs): Writing, Reviewing, Distributing & Amending SOPs for the Department of Clinical Research** | | | | |
|  | NAME | **SIGNATURE** | | **DATE** |
| **PREPARED BY** |  |  | |  |
| **REVIEWED BY** |  |  | |  |
| **QA UNIT**  **AUTHORITY** |  |  | |  |
| **APPROVAL**  **AUTHORITY** |  |  | |  |

**1.1 Purpose**

This SOP describes the process for writing, reviewing, distributing, and amending SOPs within the Department of Clinical Research and also to provide a tool for training new personnel in the procedures by which specific activities will be performed at [Institution].

This SOP will provide clear, unambiguous instruction to conduct activities of the DOCR in accordance with the ICMR guidelines 2006, Schedule „Y” (Drugs and Cosmetic Act 1940: Amendment 20th Jan 2005), ICH (International Conference on Harmonization) Good Clinical Practice (GCP) and other regulatory guidelines

**1.2 Scope:**

This SOP covers the procedures of writing, reviewing, distributing, and amending SOPs within the Department of Clinical Research, at [Institution].

**1.3 Procedure**

[Institution] will determine the activity which requires SOPs and will appoint SOP team to formulate the SOPs. SOP team will prepare the draft of the SOPs with description of the procedure (i.e., a detailed description of all tasks to be conducted under the SOP, including when they are to be accomplished, where, and by whom). The draft SOPs will be reviewed by SOP review team (3-4 members of Department of Clinical Research Team).

Each step in the procedure should be numbered. All new or unusual terms should be defined. If an abbreviation is associated with a term, it should be placed in parentheses following the word.

1.4. **Amendments and review**

SOPs will be reviewed by the SOP review team (3-4 members Department of Clinical Research Team). The HOD, Department of Clinical Research will approve the SOPs. The SOPs will then be signed by Medical Director, [Institution] as these are for conduct of research studies at [Institution].

The SOP team will consist of Manager, Asst Manger and identified experienced Department of Clinical Research coordinator. The team will assess the request(s) for SOP revision and will:

* Propose a new, or modification in existing SOPs as needed
* Select the format and coding system for the SOPs
* Draft the SOP
* Review the draft SOP
* Submit the draft for approval
* Reviews and approves the SOPs
* Signs and date the approved SOPs
* Review Team will then review and sign and date SOP

The Department of Clinical Research Core committee:

* Co-ordinates activities of writing, reviewing, distributing, and amending SOPs.
* Maintains on file all current SOPs and the list of SOPs.
* Maintain a file of all SOP amendment requests.
* Maintains an up-to-date distribution list of each SOP circulated.
* Maintain a record of the investigators to whom SOPs are distributed
* Ensures that all members involved in conducting research at [Institution] have access to the SOPs
* Maintain a file of all previous SOPs of the Department of Clinical Research
* Assist in the formulation of SOP procedure
* Ensure that all out-of-date SOPs return to Department of Clinical Research office

**1.3.1. Identify the need for new or amendment to the SOP**

Any member of the Department of Clinical Research, SOP review team, Investigator or other research team member, can make a request for revision or notices an inconsistency/ discrepancy / has any suggestions on how to improve the existing SOPs or requests to design an entirely new SOP, can put forth his / her request by using the Request Form for Formulation of new SOP/ Revision of an SOP Form. This Formulation of new SOP/ Revision of an SOP Form are submitted to the Head of Dept, Department of Clinical Research office. If the Head of Dept (HOD) agrees to the request, the Department of Clinical Research will appoint a Designated Team. This designated team will proceed with the task of revision / formulation process of the SOP. If the HOD does not agree to the request, no further action will be taken.

The Department of Clinical Research will inform the person who made the request for modification of the SOP in writing about the decision.

**1.3.2 Appoint the SOP team**

The Department of Clinical Research will constitute an SOP team who have a thorough understanding of the ethical conduct of research studies. The SOP writing team will carry out the subsequent steps. (1.3.3-1.3.7)

**1.3.3 List of relevant SOPs**

Write down step by step all the procedures for conducting clinical research activities, devise and name each process.

Make a list of SOPs with coding format (e.g. AX1-V3/SOP01/V3)

**1.3.4 Design a format and layout**

Each SOP should be given a number and a title that is self-explanatory and is easily understood

A unique code number with the format SOP xx / Vy will be assigned to each SOP. xx is a two-digit number assigned to a specific SOP. “V” refers to version of the SOP and “y” is a number identifying the version e.g. SOP01/V2 is SOP number 01 with V=version no.01

Each Annexure (AX) is unique code with format AXn–Vp/SOP xx/Vy. e.g. AX1– V2/SOP01/V2 indicates AX is Annexure, 1 is Annexure no. , V2 is version 2, belonging to the SOP 01/V2

Each Appendix will be given unique code with the format APPn/Vy e.g. APP1/V2 indicates APP is Appendix, 1 is Appendix no 1 and V2 is Version no.2.

Each SOP will be prepared according to the template for Standard Operating Procedures (AX2-V3/SOP01/V3). Each page of the SOP will bear a header with the effective date which is the date of approval of the SOPs by the Department of Clinical Research and the Medical Director of the Institution.

**1.3.5 Write, Review and Approve SOP**

With reference to section 1.3.1 and 1.3.2 the draft SOP will be prepared by the SOP team

**1.3.6 Review by Consultation**

The draft SOP will be reviewed Review Team and all Investigators. The SOP should be approved by all involved in that particular task.

The final version will be forwarded to the HOD for review and approval

**1.3.7 Preparation and submission of final draft**

The SOP review team may review the draft / revised SOP. During respective Clinical Research meetings, members can put forth their suggestions / comments on the draft / revised SOP.

The suggestions agreed upon unanimously by research team members and SOP review team will be incorporated and the final draft SOP will be formulated.

The SOP team would stand automatically dissolved once the HOD takes the final decision regarding the SOP.

**1.3.8 Final Approval of new/revised SOP**

The final version will be presented to the HOD for review and approval. The HOD will sign and date the SOP on the first page of the SOP document.

This approved document will then be submitted to the Medical Director, [Institution] for acceptance. This date of approval is declared as the effective date for implementing the SOP.

**1.3.9 Implementation, distribution and filing of SOPs**

Approved SOPs will be implemented from the effective date.

The HOD will discuss the approved SOPs with the Investigators and instruct them to implement the SOP accordingly.

Approved SOPs will be distributed to the relevant Team and notified to the distribution list (AX4 – V3/SOP 01/V3)

When revised version is distributed, the old version will no longer be effective. A copy of the old version will be archived in a master file.

One complete original set of current SOPs will be archived in the SOP master file, by the CRS and maintained in the CRS Office.

Photocopies made from the paper versions of the SOP will be considered official only if stamped and signed by the Department of Clinical Research or authorized individual. A distribution log should be maintained (AX6 –V3/SOP 01/V3)

**1.3.10 Review and request for revision of an existing SOP**

Any member of the research team who notices that current SOPs have some lacunae or have any suggestions to improve a procedure should make a written request, using a form (AX5-V3/SOP 01/V3).

If the designated Research Team agrees with the request, the HOD will appoint an appropriate team for the revision process.

If the committee does not agree, the HOD will inform the concerned individual who made the request for revision.

Revised SOPs will be reviewed and approved as per Section 1.3

The HOD will initialize the review of the SOP at least once every 2 years and records the dates of review in the SOP master file.

**1.3.11 Manage and archive old SOPs**

Old SOPs should be retained and clearly marked “superseded” and archived in a file by the secretariat. The process of evolution of previous SOPs will be documented in a defined format (AX3 –V3/SOP01/V3).

**References**

1. WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) Retrieved from - www.who.int/tdr/publications/publications / accessed 24 March 2008

2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) (1996) Retrieved form - http://www.ich.org/LOB/media/MEDIA482.pdf accessed on 24 March 2008

3. ICMR Ethical Guidelines (2006) Retrieved from -March 2008 for Biomedical research on Human Participants, ICMR http://www.icmr.nic.in/ethical guidelines.pdf accessed 24

4. Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005) Retrieved from - http://www.cdsco.nic.in/html/Schedule-Y 20 (Amended 20Version-2005) accessed 24 March 2008

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